Comorbid Opioid Use Disorder & Chronic Non-cancer Pain Practice Guidance

The amended *Mental Health Services Protection Regulation* (MHSPR) under the Mental Health Services Protection Act (MHSPA) includes new guidance and requirements for prescribers treating individuals with severe opioid use disorder (OUD) whose treatment with evidence-informed opioid agonist treatment (OAT) medications has been unable to stabilize their condition. The MHSPR and Community Protection and Opioid Stewardship (CPOS) Standards (CPOSS) set the minimum requirements that a licensed Narcotic Transition Service (NTS) provider must comply with in the provision of designated narcotic drugs (DND) for the treatment of OUD.

Delivered through Recovery Alberta's licensed Opioid Dependency Programs (ODP), NTS involves DND to help people with severe OUD who have not been able to initiate or stabilize on conventional treatment medications. Services focus on stabilizing, tapering, and transitioning patients under expert medical supervision to evidence-informed OAT medications.

Under the MHSPR, DND are defined as "any full agonist opioid drug except methadone or slow-release oral morphine (SROM)". For the purpose of treating OUD, this means:

- Buprenorphine formulations, methadone, or SROM (including M-Eslon) are not DND and are considered to be *out-of-scope* medications.
- Hydromorphone, fentanyl, and diacetylmorphine are approved DND medications for the treatment of OUD.

Individuals with OUD commonly have comorbid chronic non-cancer pain (CNCP) as a component of their condition and can also experience episodes of acute pain (unexpected and/or planned [i.e., surgery]).

This document guides practitioners on evidence-informed screening, assessment, evaluation, and ongoing monitoring of individuals with comorbid OUD/CNCP. The aim is to ensure that individuals receive safe and effective treatment with DND in compliance with the MHSPR and CPOSS. It applies to prescribers in both non-licensed (community) and licensed (Recovery Alberta) ODP/NTS clinics.

For inquiries on the treatment of comorbid OUD/CNCP, email AddictionMedicine.Resources@recoveryalberta.ca.

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Screening for OUD in Patients with CNCP

The following validated screening instruments are recommended to help practitioners determine the risk for OUD in patients prescribed opioids and/or being considered for opioid therapy.

1. ORT (Opioid Risk Tool)
2. POMI (Prescription Opioid Misuse Index)
3. SOAPP (Screener and Opioid Assessment for Patients with Pain)
4. COMM (Current opioid misuse measure)

Note: These are all brief, self-administered tests.

Diagnosing OUD and CNCP

Diagnosing OUD:

A diagnosis of OUD is to be determined by utilizing the DSM-5-TR criteria. Please see the *DSM-5-TR OUD Checklist*

The following list of behaviours assists practitioners in determining the diagnosis of an OUD. These include but are not limited to the following[1]:

1. Taking medication by route other than prescribed
2. Active concurrent addiction to alcohol and other substances
3. Diversion and other higher-risk behaviours
4. Selling, stealing, or “borrowing” prescription drugs, forgery, or obtaining prescription drugs from non-medical sources
5. Expression of affection for the medication (e.g., individual loves their medication)
6. Rapid escalations of opioid medication use
7. Multiple-dose escalation or other non-adherence with therapy despite warnings (i.e., finishing prescription earlier than the prescribing period/request for early refills)
8. Multiple episodes of prescription loss
9. Repeatedly seeking prescriptions from other prescribers after being advised to desist
10. Deteriorating functioning despite increasing doses
11. Deterioration in the ability to function at work, in the family, or socially that is related to drug use
12. Tampering with prescriptions

Diagnosing CNCP

For the diagnosis of chronic pain, the following steps are recommended:

1. Complete review of the patient's history on Connect Care and/or Netcare for previous consultants’ reports, prior diagnosis of specific chronic pain syndrome, hospitalizations as well as radiological evidence
2. A complete history and physical performed by the current practitioner

3. A formal diagnosis/formulation for the chronic pain condition and important drivers including biopsychosocial factors
4. Assessment of chronic pain and its impact on function, mental health, sleep, etc. utilizing a validated assessment tool such as the Brief Pain Inventory[2] or The Neuropathic Pain Questionnaire (NPQ)

CNCP

In alignment with the *Guideline for Opioid Therapy and Chronic Non-Cancer Pain*[3], opioids may be considered only after optimization of non-pharmacological and non-opioid pharmacological medications as identified in recommendations 1 and 3:

- Recommendation 1: When considering therapy for patients with chronic non-cancer pain, ***we recommend optimization of non-opioid pharmacotherapy and non-pharmacologic therapy, rather than a trial of opioids*** (strong recommendation)
- Recommendation 3: For patients with chronic non-cancer pain with an active substance use disorder, ***we recommend against the use of opioids*** (strong recommendation)

Community Prescribers: Comorbid OUD and CNCP

This section is intended to address individuals with comorbid OUD/CNCP who are receiving OAT from a clinic or program that is not licensed to provide NTS (e.g., community pharmacists, ODPs, family physicians or nurse practitioners, etc.), for the treatment of OUD. OAT and DND for treatment of CNCP and/or acute pain may be initiated, increased, or used with other pain management strategies to manage CNCP and/or acute pain and treat their OUD. Prescribers should carefully consider prescription and non-prescription pain management methods to determine the most suitable medication and dosage for patients. Non-pharmacologic treatments should be maximized, and thoroughly explored.

OAT

When considering treatment with OAT for the management of comorbid OUD/CNCP, prescribers may consider using buprenorphine formulations, methadone, and slow-release oral morphine (SROM). Treatment choice should be based on several factors, including patient preferences, comorbidities, treatment goals, medication efficacy, past treatments, and life circumstances.

Note: The use of evidence-informed OAT medications for pain management may be unfamiliar to some prescribers. Consultation with an Addiction Medicine Physician (AMP) via the RAAPID OUD Consultation Line is recommended.

It is recommended that individuals be trialed on OAT options before considering treatment with DND. Medication trials with both opioid and non-opioid treatment outcomes should be documented, including outcomes of pain scores, side effects, and individual function.

DND

If an individual has been diagnosed with comorbid OUD/CNCP, and if OAT options have not been successful at addressing CNCP, then DND medications may be initiated or maintained. DND should only be used to treat the individual's pain condition and not their OUD. In cases where DND are prescribed for the treatment of CNCP, clear documentation of the pain diagnosis, previous therapies and outcomes, diagnostic imaging, treatment plan, pain scoring, patient function, and other appropriate measures must be completed. Patients must be reassessed and transitioned to alternative medications unless there is clear evidence of benefit to the patient's overall function.

Section 14 of the MHSPR allows DND to be used by a prescriber authorized by their regulatory college to treat a medical condition other than OUD (i.e., acute/CNCP). Therefore, DND for the treatment of pain may be prescribed, initiated, or maintained outside of a licensed NTS facility (e.g., community pharmacy, family physician or nurse practitioner, ODPs, etc.). However, merely labeling OUD treatment as pain to allow for the use of DND outside of a licensed NTS facility is inappropriate and contrary to Alberta legislation (i.e., MHSPR) which will result in liability for the prescriber. The use of DND to treat OUD is only accessible through Recovery Alberta's ODP clinics licensed to provide NTS. Patients should be referred to an ODP clinic licensed to provide NTS closest to their location.

For the treatment of comorbid OUD/CNCP, it is advisable to use long-acting DND medication formulations for regular use. Short-acting formulations are not suggested for regular use, but rather for intermittent management of acute pain flares.

> ***Note:*** *There are conditions for which the initiation of DND is not recommended for the treatment of pain, including fibromyalgia, irritable bowel syndrome (IBS), migraine, and mechanical lower back pain.*

If DND is being considered for the treatment of CNCP, mitigation strategies to prevent inappropriate use/diversion of these medications **should be implemented**. The implementation of such strategies can include, but are not limited to, the following:

- increased dispensing frequency (e.g., daily, or weekly dispensing),
- daily witnessed ingestions

Comorbid OUD and CNCP within a licensed ODP/NTS Clinic

This section is intended to address individuals with comorbid OUD/CNCP who are receiving OAT (i.e., buprenorphine formulations, methadone, SROM) or DND (i.e., hydromorphone) for the treatment of OUD, within a Recovery Alberta ODP clinic licensed to provide NTS. OAT and DND for treatment of CNCP and/or acute pain may be initiated, increased, or used with other pain management strategies to manage CNCP and/ or acute pain and treat their OUD. Prescribers should carefully consider prescription and non-prescription pain management

methods to determine the most suitable medication and dosage for patients. Non-pharmacologic treatments should be maximized, used with, and thoroughly explored.

OAT

When considering treatment with OAT for the management of comorbid OUD/CNCP, prescribers may consider using buprenorphine formulations, methadone, and slow-release oral morphine (SROM). Treatment choice should be based on several factors, including patient preferences, comorbidities, treatment goals, medication efficacy, past treatments, and life circumstances.

It is recommended that individuals be trialed on OAT options before considering treatment with DND. Medication trials with both opioid and non-opioid treatment outcomes should be documented, including outcomes of pain scores, side effects, and individual function.

Note: The use of evidence-informed OAT medications for pain management may be unfamiliar to some prescribers. Consultation with other experienced prescribers through the RAAPID OUD Consultation Line is recommended.

DND

If an individual (1) has been diagnosed with comorbid OUD/CNCP within a clinic or program that is licensed to provide NTS, (2) is assessed by an addiction medicine physician (AMP), (3) and has not had adequate treatment outcomes with OAT options; DND may be considered for treatment of CNCP. In cases where DND is prescribed for the treatment of CNCP, clear documentation of the pain diagnosis, previous therapies and outcomes, diagnostic imaging, treatment plan, pain scoring, patient function, and other appropriate measures must be completed. Patients must be reassessed and transitioned to OAT options unless there is clear evidence of benefit to the patient's overall function.

When DND is prescribed for the treatment of OUD, it is not to be administered, dispensed, or sold in a formulation that may be taken by a patient outside of a licensed NTS program, clinic, or facility providing NTS (i.e., transdermal formulation). Practitioners working in Recovery Alberta ODP clinics licensed to provide NTS must consult with the clinic's AMP for advice and approval of treatment plans that recommend using DND to treat comorbid OUD/CNCP conditions. Such consultation is necessary to assess and diagnose an individual's OUD and CNCP and to develop a treatment plan that follows Alberta legislation.

For the treatment of comorbid OUD/CNCP, it is advisable to use long-acting DND medication formulations for regular use. Short-acting formulations are not suggested for regular use, but rather for intermittent management of acute pain flares.

> ***Note:*** *There are conditions for which the initiation of DND is not recommended for the treatment of pain, including fibromyalgia, irritable bowel syndrome (IBS), migraine, and mechanical lower back pain.*

DND Medications Approved within ODPs Licensed to provide NTS

Hydromorphone

Hydromorphone is the primary DND prescribed within Recovery Alberta's ODP clinics licensed to provide NTS. Medication administration routes can include oral, intramuscular, or intravenous. Hydromorphone must be prescribed, administered, and dispensed within the location at which NTS is provided.

Fentanyl

Fentanyl, in oral or intravenous formulations, requires additional approval from the PMDA and must be prescribed, administered, and dispensed within the location at which NTS is provided.

Transdermal formulations (i.e., fentanyl patch) will not be approved for the treatment of OUD. However, with PMDA approval, transdermal formulations may be initiated or maintained for individuals with comorbid OUD/CNCP ***if*** the purpose is to treat the individual's pain condition and not their OUD. Prescribers are to complete and submit the Fentanyl Prescribing Approval Form for PMDA review/approval before treatment initiation.

- It is recommended, for clarity of prescribers, staff, patients, and health services inspectors that transdermal fentanyl patches, for the treatment of CNCP, be administered away from where NTS services (DND medications) are provided (e.g., mobile OAT teams, at the ODP side of an ODP/NTS clinic, or in a community pharmacy). This ensures that all NTS care participants understand that no DND medications leave the site with the patient.

Diacetylmorphine (DAM)

DAM is currently unavailable in Alberta and may be considered in the future depending on need and availability.

Additional DND Medications

During treatment, individuals with comorbid OUD/CNCP may require additional DND (i.e., Meperidine, Tramadol, Codeine) not typically used in licensed NTS clinics. Additional DND medications may be prescribed for the treatment of CNCP, however, it is recommended, for clarity of prescribers, staff, patients, and health services inspectors that additional DND medications, for the treatment of CNCP, be administered away from where NTS services (DND medications) are provided. This ensures that all NTS care participants understand that no DND medications for the treatment of OUD leave the site with the patient.

Mitigation Strategies

If DND is being considered, mitigation strategies to prevent inappropriate use/diversion of these medications **must be implemented.**

The implementation of such strategies can include, but are not limited to, the following:

- increased dispensing frequency (e.g., daily dispensing),
- daily witnessed ingestions

- mouth checks for tablet medications
    - The practice of mouth checks to reduce the risk of diversion is ethically implemented in all ODP clinics licensed to provide NTS. It is done consistently with all NTS patients and is explained in a transparent and compassionate manner; respectful of the patient's autonomy and personhood.

The following mitigation strategies to prevent tampering/diversion should be implemented when transdermal fentanyl is prescribed for the treatment of CNCP:

- witnessed patch changes
- utilization of Tegaderm, signed and dated by the person changing the patch.

Comorbid OUD//CNCP Monitoring

If DND is prescribed for treatment of comorbid OUD/CNCP, regular monitoring is required, including:

Pain Assessment

The assessment of pain rating/relief, improvement in function, and adverse effects should be conducted at least monthly, and documented utilizing the Brief Pain Inventory or another validated instrument/documentation method.

Medication Adherence

Regular review of the treatment plan/prescribed medication to ensure ongoing benefit to the individual in treating comorbid OUD/CNCP and in compliance with the MHSPR and CPOSS.

Urine Toxicology Screens

Regular urine drug screening shall be performed at reasonable clinical intervals until significant sustained stability is demonstrated. It is important to exercise caution when prescribing fentanyl. The prevalence of fentanyl and its analogs within the unregulated drug supply makes it difficult to distinguish unregulated fentanyl from prescribed fentanyl within urine toxicology screens.

De-Prescribing: DND

If there is no documented improvement in pain or function from an individual's baseline and/or if there is evidence of adverse effects from prescribing DND, then de-prescribing should be considered and discussed with the patient.

When considering de-prescribing DND medications, it is important to involve the patient in the decision-making process. This should be done after carefully evaluating the patient's preferences, concurrent conditions, treatment/recovery objectives and goals, medication efficacy, past medication history, and life circumstances. De-prescribing should be done with sensitivity and care, not as a punishment. It is crucial to meet the patient's self-identified needs

to maintain treatment adherence, decrease unregulated opioid use, and reduce the likelihood of morbidity and mortality.

> **Note:** Treatment for patients with comorbid OUD/CNCP follows a stepped approach, which means that the intensity of the treatment is increased gradually as necessary. Before de-prescribing DND medication for OUD/CNCP, the health care provider must carefully consider the effectiveness of past medications and take all the necessary precautions to avoid initiating a medication that did not work for the patient in the past.

Decision-Making & Practice Supports

The treatment and management of comorbid OUD/CNCP is complex. OUD Consultation with an AMP colleague and/or the PMDA is recommended.

Continuing Medical Education (CME) accredited learning on the comprehensive assessment and management of comorbid OUD and CNCP is accessible via the PACES Learning Pathway.

- EPA-Sim: Chronic Non-Cancer Pain Part 1: Comprehensive Assessment
- EPA-Sim: Chronic Non-Cancer Pain Part 2: Comprehensive Pain Management and De-Prescribing Opioids
- Opioid Use Disorder and Chronic Non-Cancer Pain Video Lectures Playlist

References

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2. Reliability and validity of a modified Brief Pain Inventory short form in patients with osteoarthritis Doi: 10.1016/j.ejpain.2005.06.002. Epub 2005 Jul 26.
3. Guideline for opioid therapy and chronic noncancer pain CMAJ May 08, 2017, 189 (18) E659-E666; DOI: https://doi.org/10.
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